IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| WYETH,<br><br>Plaintiff,<br><br>v.<br><br>IMPAX LABORATORIES, INC.,<br><br>Defendant. | ) | Civil Action No.: 06-222 JJF |

**DEFENDANT IMPAX LABORATORIES, INC.'S BRIEF IN SUPPORT OF ITS MOTION TO COMPEL PRODUCTION OF DOCUMENTS IN RESPONSE TO DEFENDANT'S FOURTH SET OF REQUESTS FOR PRODUCTION (NOS. 125-131)**

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## I. NATURE AND STAGE OF THE PROCEEDINGS

This case is about Wyeth's patented extended release formulation of venlafaxine, sold under the brand name EFFEXOR XR®. Wyeth's patents claim that administration of its extended release formulation results in "diminished incidence(s) of nausea and emesis." *See* Declaration of Mary B. Matterer in Support of Defendant Impax Laboratories, Inc.'s Motion to Compel Production of Documents in Response To Defendant's Fourth Set of Requests for Production (Nos. 125-131) ("Matterer Decl."), Ex. A at Col. 12, line 63 – Col. 13, line 3. To defend itself against Wyeth's infringement allegations, Impax Laboratories, Inc. ("Impax") continues to seek efficient discovery of the factual bases for this and other statements Wyeth made in the patents-in-suit and assertions it has made in this action, so as to dispose of this case as quickly as possible. The issue is whether Wyeth should be permitted to block discovery of an area which it placed in issue and is important to patent validity, inequitable conduct and commercial success.

Wyeth has begun the process of shifting the market from the Effexor XR® product to ***a chemically-related follow-on product***, desvenlafaxine succinate, or O-desmethylvenlafaxine (to be sold under the brand name Pristiq®). *See* Matterer Decl., Ex. B at 3[1]; *id.*, Ex. C at 1. Desvenlafaxine succinate, also known as O-desmethylvenlafaxine ("desvenlafaxine") is the active metabolite of venlafaxine[2], the active ingredient of the extended release formulation at issue in this case.

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[1] This article incorrectly identifies GlaxoSmithKline as the company that sells Effexor XR® and is developing the desvenlafaxine product.

[2] When Effexor XR® is broken down in the liver, the most significant resulting chemical product is desvenlafaxine. *See* Matterer Decl., Ex. K at 2 ("venlafaxine is well absorbed and extensively metabolized in the liver. O-desmethylvenlafaxine (ODV) is the only major active metabolite" of venlafaxine). Significantly, studies show that desvenlafaxine ***has the same effects on the same neurotransmitters*** as Effexor XR®. *See* Matterer Decl., Ex. K at 2 ("[p]reclinical studies have shown that venlafaxine and its

*(Footnote continued)*

Impax has propounded seven Requests for Production purposely limited to two specific categories of documents: (1) clinical documents that demonstrate comparisons of Effexor XR® and the desvenlafaxine metabolite on the critical variable of nausea and emesis (vomiting), on which many asserted claims of the patents-in-suit rest; and (2) advertising and marketing documents that demonstrate such comparisons between Effexor XR® and desvenlafaxine on nausea and emesis or other marketable features. *See* Matterer Decl., Ex. D. In other words, ***each and every disputed Request seeks documents concerning Effexor XR®, the extended release formulation covered by the patents-in-suit***. After a meet and confer, Wyeth refused to acknowledge that the requested documents could lead to admissible evidence and has refused to produce such documents, prompting this motion.

## II. FACTUAL BACKGROUND

### A. Wyeth Filed This Patent Infringement Case Against Impax Asserting Infringement Of The Extended Release Venlafaxine Product Sold As Effexor XR®

The patents-in-suit describe and claim an extended release formulation of venlafaxine limited to specific ingredients which, *inter alia*, purportedly provides a "diminished incidence of nausea and emesis." *See* Matterer Decl., Ex. A at Col. 12, line 63 – Col. 13, line 3. The truth and accuracy of this claimed effect of Wyeth's venlafaxine formulation is a major factual issue that is critical to several important legal issues in this case. Accordingly, Impax has attempted to discover information relating to Wyeth's bases for making this representation to the Patent Office regarding nausea and emesis. Naturally, clinical studies of the formulation that test these variables are highly relevant to this issue, or at the very least, reasonably calculated to lead to admissible evidence.

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active metabolite, O-desmethylvenlafaxine (ODV), are potent inhibitors of neuronal serotonin and norepinephrine reuptake and weak inhibitors of dopamine reuptake").

Wyeth has also asserted that the commercial success of Effexor XR® is due to the claimed features of the invention, particularly to the reduced nausea and emesis profile the product purportedly achieves in patients. *See* Matterer Decl., Ex. E at 28. Therefore, marketing plans concerning Effexor XR® and desvenlafaxine that discuss nausea and emesis caused by Effexor XR® are relevant to the commercial success issue, or at least likely to lead to admissible evidence. Finally, clinical studies comparing the side effect profiles would bear on whether Effexor XR® actually achieves the result of providing a diminished incidence of nausea and vomiting and would therefore be relevant to unexpected results, an issue in the obviousness analysis.

### B. Wyeth Receives FDA Approval For Desvenlafaxine As A Follow-On Product To Effexor XR®

There is no dispute that Wyeth has received FDA approval to market desvenlafaxine to treat depression [*See* Matterer Decl., Ex. F] and that desvenlafaxine was developed as a replacement for the parent compound, venlafaxine. *See* Matterer Decl., Ex. B at 3. Moreover, a series of published abstracts reported clinical studies of desvenlafaxine, including some nausea data similar to the Effexor XR data at issue in this case. *See* Matterer Decl., Ex. C at 1-2.

### C. Impax Requests Clinical And Marketing Documents Relating To Comparisons Of Effexor XR® And Desvenlafaxine Nausea And Vomiting Side Effects

Published reports of this chemically-related follow-on compound and the studies exploring some of the same parameters as those claimed in the patents-in-suit have made desvenlafaxine information extremely relevant. So Impax served its Fourth Set of Requests for Production directed to clinical and marketing documents concerning Effexor XR® and desvenlafaxine and the variables of nausea and vomiting *See* Matterer Decl., Ex. D. These Requests seek documents relevant to, *inter alia*, inequitable conduct and obviousness issues. The Requests are reproduced below. Six out of seven are targeted to nausea and emesis information, and ***they all are directed to Effexor XR® information***:

REQUEST NO. 125:

DOCUMENTS CONCERNING all studies, tests, trials, research, or experiments conducted ***that compare nausea and emesis*** between patients receiving ***EFFEXOR XR*** or any WYETH EXTENDED RELEASE FORMULATION comprising VENLAFAXINE and patients receiving DESVENLAFAXINE, including without limitation all DOCUMENTS sufficient to IDENTIFY all PERSONS who have knowledge of such studies, tests, trials, research, or experiments, what knowledge each PERSON has, and all DOCUMENTS that evidence or refute such studies, tests, trials, research, or experiments.

REQUEST NO. 126:

DOCUMENTS submitted to the FDA and/or to the PTO ***that compare nausea and emesis*** between patients receiving ***EFFEXOR XR*** or any WYETH EXTENDED RELEASE FORMULATION comprising VENLAFAXINE and patients receiving DESVENLAFAXINE.

REQUEST NO. 127:

DOCUMENTS CONCERNING any and all statistical analyses conducted by, or on behalf of, or at the request of, in the custody or possession of WYETH, ***that compare nausea and emesis*** between patients receiving ***EFFEXOR XR*** or any WYETH EXTENDED RELEASE FORMULATION comprising VENLAFAXINE and patients receiving DESVENLAFAXINE.

REQUEST NO. 128:

All DOCUMENTS CONCERNING marketing plans for DESVENLAFAXINE ***that compare nausea and emesis*** between patients receiving ***EFFEXOR XR*** or any WYETH EXTENDED RELEASE FORMULATION comprising VENLAFAXINE and patients receiving DESVENLAFAXINE.

REQUEST NO. 129:

All education plans and DOCUMENTS to be provided to physicians or patients ***that compare nausea and emesis*** between patients receiving ***EFFEXOR XR*** or any WYETH EXTENDED RELEASE FORMULATION comprising VENLAFAXINE and patients receiving DESVENLAFAXINE.

REQUEST NO. 130:

All publications, including without limitation, U.S. and foreign patents, textbooks, articles, conference proceedings, treatises, theses,

> tutorials, speeches, and presentations, ***that compare nausea and emesis*** between patients receiving ***EFFEXOR XR*** or any WYETH EXTENDED RELEASE FORMULATION comprising VENLAFAXINE and patients receiving DESVENLAFAXINE.
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> REQUEST NO. 131:
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> All DOCUMENTS CONCERNING marketing plans or strategy to transition the market for ***EFFEXOR XR*** to any Wyeth formulation comprising DESVENLAFAXINE.

Matterer Decl., Ex. D at 7-8 (emphasis added).

### D. Wyeth Refuses To Acknowledge The Relevance Of Documents Concerning Both Effexor XR® And Desvenlafaxine And Refuses To Even Search For Any Responsive Documents

In Plaintiff's Responses and Objections to Impax's Fourth Request for Production of Documents and Things, served March 29, 2007, Wyeth objected to the Requests on a number of grounds (principally relevance) and indicated that it would not produce any responsive documents. *See* Matterer Decl., Ex. G. Impax promptly scheduled a meet and confer on the subject and explained to Wyeth's counsel why the requested documents were at least likely to lead to admissible evidence on inequitable conduct and obviousness and quite likely to contain relevant evidence. *See* Matterer Decl., Ex. H. Wyeth's counsel refused to acknowledge that the Effexor XR® / desvenlafaxine information could even lead to admissible evidence and suggested that the parties "agree to disagree" as to the relevance of the requested documents. *See* Matterer Decl., Ex. H; Ex. I at 2-3. In fact, Wyeth's counsel refused to identify the quantity or whereabouts of documents in the requested categories, and Wyeth has indicated that it will not even conduct a reasonable search for the documents.[3] [4] *See* Matterer Decl., Ex. H.

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[3] In another example of Wyeth's delay tactics, Wyeth took the full 30-day period to inform Impax that it had not, and would not, conduct a reasonable search for the requested documents.

[4] It seems highly likely that such documents exist. ***Wyeth's own patent covering desvenlafaxine succinate, U.S. Patent No. 6,673,838, discloses a clinical trial***

*(Footnote continued)*

Accordingly, Impax brings this motion. Impax respectfully requests that this Court put an end to Wyeth's delay tactics and order Wyeth to produce any and all documents responsive to Impax's Fourth Set of Requests for Production within 30 days.

## III. SUMMARY OF ARGUMENT

This case is about Effexor XR®, the commercial embodiment of Wyeth's venlafaxine extended release formulation claimed in the patents-in-suit. Wyeth made statements to the Patent Office to persuade the Patent Office that its formulation was a patentable invention. In both the claims and the specification of the patents themselves, Wyeth represented that administration of its claimed extended release formulation provides "diminished incidence(s) of nausea and emesis." Naturally, whether the formulation actually achieves this result is critical to several issues in this case, including patent validity, inequitable conduct and commercial success. With respect to commercial success, a so-called "secondary consideration" of nonobviousness, this issue turns on whether sales of Effexor XR® are due to the claimed features of the invention, of which diminished incidence of nausea and vomiting is one of the most important. Indeed, Wyeth has asserted that the commercial success of Effexor XR® is attributable to the claimed features of the invention. *See* Matterer Decl., Ex. E at 28. By contrast, Impax's position is that any alleged commercial success is due to advertising and promotion. *See* Matterer Decl., Ex. L at 10-11.

The Requests for Production at issue here are also about Effexor XR®. More particularly, these Requests concern documents that compare nausea and emesis between patients receiving Effexor XR® and desvenlafaxine, either clinically or from an advertising and marketing perspective. *See* Matterer Decl., Ex. D at 7-8. Request No.

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***comparing Effexor XR® and desvenlafaxine in which the number of subjects experiencing nausea caused by administration of desvenlafaxine was tabulated.*** *See* Matterer Decl., Ex. J at Col. 29, line 15 – Col. 31, line 20.

131 seeks documents relating to Wyeth's attempts to transition the market for Effexor XR® to the desvenlafaxine product. *See id.*, Ex. D at 8. Documents responsive to this Request are relevant to the lack of nexus between the patented invention and any alleged commercial success because they would address marketable features of both Effexor XR® and the desvenlafaxine product and relative drawbacks of each from a promotional perspective, including claimed features of the extended release venlafaxine.

The Federal Rules of Civil Procedure permit broad discovery of evidence reasonably calculated to lead to admissible evidence. *See Pettingill v. Caldwell*, 2006 U.S. Dist. LEXIS 58651, *4 (D. Del. Aug. 21, 2006) (Farnan, J.) ("I am persuaded that the challenged documents are reasonably calculated to lead to the discovery of admissible evidence, and therefore, they meet the minimum requirements for relevance under Federal Rule of Civil Procedure 26(b)(1)"); *Jurimex Kommerz Transit GMBH v. Case Corp.*, 2005 U.S. Dist. LEXIS 2827, *7 (D. Del. Feb. 18, 2005) (Farnan, J.) ("The Federal Rules of Civil Procedure allow for a broad scope of discovery that is not limited to admissible evidence, but evidence that is reasonably calculated to lead to the discovery of admissible evidence"). As will be discussed below, the requested documents at issue here well exceed this standard.

## IV. ARGUMENT

### A. This Case Is About Effexor XR® And These Requests Are About Effexor XR®

#### 1. Relevance To Validity: The Patents Claim An Extended Release Formulation Of Venlafaxine, Embodied In The Effexor XR® Product, That Provides "Diminished Incidence(s) Of Nausea And Emesis"

Wyeth alleges that Impax's venlafaxine product infringes certain claims of U.S. Patent No. 6,274,171 (the "'171 patent"), U.S. Patent No. 6,403,120 (the "'120 patent"), and U.S. Patent No. 6,149,958 (the "'958 patent") directed to an extended release formulation of venlafaxine embodied in the Effexor XR® product. Claims 20, 22 and 23

of the '171 patent, claims 1, 2, 13 and 14 of the '120 patent and claims 1, 3 and 4 of the '958 patent recite administration of Wyeth's extended release formulation to provide a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period "with diminished incidence(s) of nausea and emesis." *See* Matterer Decl., Ex. A at Col. 12, line 63 – Col. 13, line 3. The following claim is representative:

> 20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period ***with diminished incidences of nausea and emesis*** which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

Matterer Decl., Ex. A at Col. 12, line 63 – Col. 13, line 3 (emphasis added).

In view of Wyeth's focus on the formulation's claimed reduction in nausea and vomiting, the question of whether the drug actually achieves this result is paramount to properly resolving the issues in this case. Studies that compare nausea and emesis between patients who receive the Wyeth extended release venlafaxine formulation, sold as Effexor XR®, and patients who receive desvenlafaxine would necessarily include nausea and emesis data that may show the claimed formulation does not reduce those side effects, rendering the invention inoperative and the patent claims invalid. The data would also contradict Wyeth's representations to the Patent Office and in this litigation regarding the alleged "diminished incidence." Wyeth has placed this issue in controversy and must now produce all documents that could prove or disprove or frame the issues relating to it. By targeting Effexor XR® / desvenlafaxine nausea and emesis comparisons, the disputed Requests seek such relevant documents.

**2. Relevance To Inequitable Conduct: The Patents' Specification Discloses Reduced Nausea And Makes Representations That The Extended Release Formulation Embodied In Effexor XR® Provides A "Statistically Significant" Reduction In Nausea And Emesis**

Wyeth's assertions about the purported "diminished incidence(s)" do not end with the claims. Wyeth raised the stakes by representing to the Patent Office (in a statement

that ultimately appears in the issued patents' specification) that its claimed extended release formulation showed a "statistically significant improvement" over the immediate release venlafaxine in three clinical studies. *See* Matterer Decl., Ex. A at Col. 2, lines 52-55. The specification also asserts that the invention provides a method for reducing nausea and emesis:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. ***Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies***. Thus, in accordance with this use aspect of the invention ***there is provided a method for reducing the level of nausea and incidence of emesis*** attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

Matterer Decl., Ex. A at Col. 2, lines 46-62.

As one basis for its inequitable conduct defense, Impax alleges that Wyeth falsely told the Patent Office that three clinical studies showed a statistically significant reduction in the incidence of nausea. These studies were used to convince the Patent Office to grant the patents. To determine whether Wyeth accurately represented the information regarding nausea and emesis rates to the Patent Office, and whether the studies themselves accurately represent the side effect profile of Effexor XR®, Impax needs access to Effexor XR® nausea and emesis data. Thus, the Requests for Production regarding clinical data ***specifically request only documents concerning nausea and emesis***. As discussed above, studies that compare nausea and emesis between patients who receive the Wyeth extended release venlafaxine formulation and patients who receive desvenlafaxine would necessarily include nausea and emesis data that may contradict Wyeth's representations regarding the alleged "diminished incidence" and the clinical data Wyeth cited to the Patent Office. Should such contradictions come to light,

Wyeth would be guilty of violating its duty of candor to the Patent Office, and the patents-in-suit may be unenforceable due to inequitable conduct.

**3. Relevance To Commercial Success: Documents Comparing Nausea And Emesis Data For Effexor XR® To The Follow-On Desvenlafaxine Product Would Tend To Show Nexus (Or Lack Thereof) To The Claimed Features**

As mentioned above, this case is about Effexor XR® and the claimed features of the extended release venlafaxine formulation embodied by that product. This holds true for the issue of commercial success, a so-called "secondary consideration" of non-obviousness. Impax contends that the patents-in-suit are invalid because certain prior art references render the claims obvious. In other words, the information in the patents would have been obvious to a person of skill in the art based on what was in the public domain when Wyeth's initial patent application was filed. Wyeth counters that the alleged commercial success of its Effexor XR® product proves that the claimed extended release formulation is not obvious over the prior art. The critical issue in the commercial success analysis is whether the alleged commercial success of Effexor XR® is attributable to the claimed features of the invention or to unclaimed features and/or advertising campaigns. *See Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("[a] nexus between commercial success and the claimed features is required").

Impax maintains that any alleged commercial success is due to advertising and promotional messages and unclaimed features of the drug. Thus, marketing plans and strategy that mention Effexor XR® are highly relevant to the alleged commercial success of the claimed inventions. In addition, because Wyeth is preparing to release the desvenlafaxine product, its devised strategies to transition the market to this follow-on product likely address Effexor XR®'s selling strengths and weaknesses and may establish whether its sales are due to advertising and promotional efforts or the claimed features of the invention. Accordingly, Requests for Production Nos. 128, 129 and 131

are targeted to marketing and promotional documents concerning nausea and emesis comparisons of Effexor XR® and desvenlafaxine and Wyeth's plans to transition the market from the venlafaxine product to the desvenlafaxine product.[5] *See* Matterer Decl., Ex. D at 7-8.

### B. Independent Of Effexor XR®, Desvenlafaxine Itself Is Relevant As An Active Metabolite Of The Venlafaxine Compound In Effexor XR®

Even standing alone, desvenlafaxine clinical data is reasonably calculated to lead to admissible evidence in this case because it is a chemically-related follow-on product to Effexor XR® which is also purported to provide reductions in nausea and vomiting. *See* Matterer Decl., Ex. J at Col. 30, line 67 – Col. 31, line 20. Specifically, it is the only major active metabolite of venlafaxine, the active ingredient of Effexor XR®. *See* Matterer Decl., Ex. K at 2 ("O-desmethylvenlafaxine (ODV) is the only major active metabolite" of venlafaxine). In other words, when Effexor XR® is broken down in the liver, the most significant resulting chemical product is desvenlafaxine. *See* Matterer Decl., Ex. K at 2 ("venlafaxine is well absorbed and extensively metabolized in the liver. O-desmethylvenlafaxine (ODV) is the only major active metabolite" of venlafaxine).

Significantly, studies show that desvenlafaxine ***has the same effects on the same neurotransmitters*** as Effexor XR®'s active ingredient, venlafaxine. *See* Matterer Decl., Ex. K at 2 ("[p]reclinical studies have shown that venlafaxine and its active metabolite, O-desmethylvenlafaxine (ODV), are potent inhibitors of neuronal serotonin and norepinephrine reuptake and weak inhibitors of dopamine reuptake"). Thus, it is far from clear that venlafaxine itself is solely responsible for the effects Wyeth has claimed in the

[5] It is worth noting that Wyeth arguably was already under a duty to produce some Effexor XR® marketing documents embraced by the Requests for Production at issue here because of its obligation to supplement production in response to Impax's prior Requests for Production 76 and 77 of Impax's Second Set of Request for Production and Request 88 of Impax's Third Set of Requests for Production, which seek Effexor XR® business, financial and marketing documents.

patents-in-suit. It appears that venlafaxine may cause some therapeutic effects and side effects, while the metabolite desvenlafaxine may independently contribute to the results achieved by Effexor XR®.

Either independently or viewed in tandem with Effexor XR®, the requested comparison data would tend to show whether the Effexor XR® product truly demonstrates an improvement in nausea and emesis in the progression of the venlafaxine family of drugs. Thus, the requested documents are reasonably calculated to lead to admissible evidence by rounding out and completing the full Effexor XR® nausea "story" even beyond the obvious immediate relevance that would be gleaned from Effexor XR® nausea data alone.

### C. Wyeth's Desvenlafaxine Patent Discloses That Responsive Documents Likely Exist

Finally, as mentioned above, Wyeth has admitted that there probably are documents responsive to the disputed Requests. In Wyeth's own patent, U.S. Patent No. 6,673,838, the specification discloses a clinical trial comparing Effexor XR® and desvenlafaxine. *See* Matterer Decl., Ex. J at Col. 29, line 15 – Col. 31, line 20. This study tabulated the number of subjects suffering adverse events, ***including nausea***, after administration of desvenlafaxine. *See* Matterer Decl., Ex. J at Col. 30, line 67 – Col. 31, line 20.

## V. CONCLUSION

For the foregoing reasons, Impax respectfully requests that the Court grant its motion to compel production of documents responsive to Impax's Fourth Set of Requests for Production (Nos. 125-131).

April 10, 2007

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